

42 (16.0%) patients self monitor their glucose level. The most frequently reported factor affecting adherence is high cost of drug therapy, 118 (44.8%), and forgetfulness, 99 (37.6%). Most of the patients, 201 (76.4%), have developed one complication or the other such as hypertension and glaucoma. **CONCLUSIONS:** There is poor adherence to anti-diabetic therapy among the patients. Financial constraint was found to be the most important factor affecting optimal adherence to therapy.

#### PDB66

##### NEED FOR CASE-MIX ADJUSTMENT IN EVALUATING GEOGRAPHIC DISPARITIES IN MEDICATION ADHERENCE TO ORAL HYPOLYCEMICS

Shah R<sup>1</sup>, Banahan BFI<sup>1</sup>, Hardwick S<sup>2</sup>, Clark J<sup>2</sup>

<sup>1</sup>University of Mississippi, University, MS, USA, <sup>2</sup>Mississippi Division of Medicaid, Jackson, MS, USA

**OBJECTIVES:** To examine adherence to oral hypoglycemics among Mississippi Medicaid beneficiaries and to evaluate the need for case-mix adjustment when examining disparities among counties. **METHODS:** The study was a retrospective analysis of Mississippi Medicaid claims data from 2008-2011. Beneficiaries were included in the analysis if they had at least two claims for oral hypoglycemics, had 90 or more days of therapy, were at least 18 years old, were not dual-eligible, and were not in long term care. Medication adherence was measured using Proportion of Days Covered (PDC) with a gap of 60 days being considered a discontinuation of therapy. PDC was calculated for each drug being taken and an average PDC was computed for each beneficiary for the time on any therapy. Beneficiaries with a PDC greater than 80% were considered to be compliant to therapy. Overall comorbidity was measured with an RxRisk score. Percentage of beneficiaries compliant in each county was calculated. Counties were classified as high, medium and low compliance. A multivariable logistic regression model was used to assess the relationship between compliance and beneficiaries' age, sex, race and comorbidities. The relationships among county compliance level and beneficiary characteristics associated with compliance were evaluated to determine case-mix confounders that need to be adjusted for in evaluating county level disparities. **RESULTS:** Percentage of compliant beneficiaries in the counties ranged from 33.3% to 66.7%. Beneficiary characteristics related to compliance were gender (odds ratio for male to female = 0.870), race (odds ratio for African-Americans to Caucasians = 0.647), and RxRisk score (odds ratio for score of 0 to 6+ = 0.717). Race and RxRisk scores were significantly related to county compliance levels. **CONCLUSIONS:** Beneficiary characteristics are strong predictors of compliance. Any evaluation of county level disparities in adherence rates must use adjustments for variations in the patient mix among the counties.

#### PDB67

##### ASSOCIATIONS BETWEEN CLAIMS BASED ADHERENCE, WEIGHT LOSS AND, GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES

McAdam-Marx C<sup>1</sup>, Bellows BK<sup>1</sup>, Wygant GD<sup>2</sup>, Mukherjee J<sup>3</sup>, Unni S<sup>1</sup>, Ye X<sup>1</sup>, Illoeje UH<sup>1</sup>, Brixner D<sup>1</sup>

<sup>1</sup>University of Utah, Salt Lake City, UT, USA, <sup>2</sup>Bristol-Myers Squibb, Princeton, NJ, USA, <sup>3</sup>Bristol-Myers Squibb, Wallingford, CT, USA

**OBJECTIVES:** The association between anti-diabetic adherence, weight loss, and glycemic control in patients with type 2 diabetes (T2DM) remains largely uncharacterized. This study examined the relationships between these variables in T2DM patients in an integrated health system. **METHODS:** This was a historical cohort study of patients treated in the Geisinger Health System. Included patients were  $\geq 18$  years, with T2DM, prescribed a class of anti-diabetic not previously prescribed (index date) between 11/1/10-4/30/11, with HbA1c and weight values at index date and 6-months follow-up, and had Geisinger Health Plan insurance with  $\geq 1$  claim for the index date medication. Anti-diabetics were grouped as weight loss (metformin and GLP-1 agonists) versus weight gain/neutral (sulfonylureas, thiazolidinediones, DPP-4 inhibitors, insulin, and others) to help control for weight effects of drug therapy. Adherence was calculated using the modified Medication Possession Ratio (mMPR) with a score  $\geq 0.8$  considered adherent. The primary outcomes were weight loss  $\geq 3\%$  and HbA1c control ( $< 7.0\%$ ) at 6 months follow-up. A structural equation model (SEM) was used to simultaneously assess the associations between claims adherence, weight loss, and HbA1c control. **RESULTS:** There were 166 patients included with a mean (SD) age of 61.1 (12.1) years, 56% were women, 98.8% were white, 58 were prescribed metformin or a GLP-1, and 108 were prescribed a sulfonylurea, thiazolidinedione, DPP-4 inhibitor, insulin, or other class. Adherence per mMPR was high with 77.1% of patients classified as adherent with no significant difference between anti-diabetic groups. Results of the SEM showed that both anti-diabetic adherence (OR 2.71 95%CI 1.22-5.98) and weight loss  $\geq 3\%$  (OR 2.99 95%CI 1.45-6.17) were associated with HbA1c control. **CONCLUSIONS:** This study adds to the body of literature highlighting the importance of weight loss and adherence in glycemic control. It also emphasizes the importance of anti-diabetic agent selection and strategies promoting adherence and weight management goals.

#### PDB68

##### ASSESSING ADHERENCE AMONG PATIENTS WITH TYPE 2 DIABETES USING INSULIN: PSYCHOMETRIC ANALYSIS OF THE MORISKY MEDICATION ADHERENCE SCALE

DiBonaventura M<sup>1</sup>, Wintfeld N<sup>2</sup>, Huang J<sup>2</sup>, Goren A<sup>1</sup>

<sup>1</sup>Kantar Health, New York, NY, USA, <sup>2</sup>Nova Nordisk, Inc., Princeton, NJ, USA

**OBJECTIVES:** The Morisky Medication Adherence Scale (MMAS) provides a unique perspective on adherence because of its patient-reported nature. However, as it is not a condition-specific instrument, evidence of its reliability and validity within the population of interest must be obtained. This study

examined the psychometric properties of the recently developed eight-item MMAS (MMAS-8) among those with type 2 diabetes (T2D) using insulin. **METHODS:** Data from the US 2012 National Health and Wellness Survey (NHWS) were used (N=71,141). Only respondents who reported a diagnosis of T2D, were currently using an insulin (any type), and reported their last value of HbA1c were included (n=1,198). Among this subsample, the reliability and validity of the MMAS-8 (when asked only about diabetes medications) were examined using both classic test theory and item response theory (IRT) analyses. **RESULTS:** A total of 61.44% of respondents were male and the mean age was 60.65 (standard deviation = 10.74). Engagement of non-adherent behaviors (the individual items of the MMAS-8) varied considerably from "stopping medication when feeling worse" (5.76%) to "having difficulty remembering to take all your medications" (32.22%). Internal consistency was adequate (Cronbach's  $\alpha=0.68$ ), though would have been improved upon removal of the "did you take your medicine yesterday" item ( $\alpha=0.70$  if removed). One factor was retained using exploratory factor analysis (eigenvalue=1.80). In IRT analyses, most items exhibited solid psychometric properties (e.g., discrimination  $> 1.40$ ); however, "did you take your medicine yesterday", provided little information (discrimination=0.20; information=0.02). Overall, the MMAS-8 functioned best when distinguishing among those with above average non-adherence ( $\theta > 0$ ). **CONCLUSIONS:** These results suggest the MMAS-8 is a reliable and valid instrument to use to assess non-adherence, though certain items are less useful than others for this population. Despite its generic nature, the MMAS-8 should be considered as an adherence measurement tool among those with T2D using insulin.

#### PDB69

##### SYSTEMATIC LITERATURE REVIEW OF UTILITIES RELATING TO PATIENTS WITH TYPE-2 DIABETES MELLITUS EXPERIENCING A STROKE OR MYOCARDIAL INFARCTION

Brennan VK<sup>1</sup>, Colosia AD<sup>2</sup>, Copley-Merriman C<sup>3</sup>, Hass B<sup>4</sup>, Palencia R<sup>5</sup>

<sup>1</sup>RTI Health Solutions, Sheffield, UK, <sup>2</sup>RTI Health Solutions, Research Triangle Park, NC, USA,

<sup>3</sup>RTI Health Solutions, Ann Arbor, MI, USA, <sup>4</sup>Boehringer Ingelheim GmbH, Ingelheim, Germany,

<sup>5</sup>Boehringer Ingelheim GmbH, Ingelheim am Rhein, Germany

**OBJECTIVES:** Patients with type-2 diabetes mellitus (T2DM) are at increased risk of stroke or myocardial infarction (MI) resulting in decrements in their health-related quality of life. A systematic literature review identified estimates of utility decrements for these events in patients with T2DM to better understand the impact of avoiding or delaying them with treatment. **METHODS:** Electronic databases (2001-2011) and conference abstracts (2009-2011) in English were searched for utility-elicitation studies in T2DM and for cost-effectiveness analyses that included disutility estimates for stroke and MI. **RESULTS:** Nine utility-estimation studies using data from 11 countries were identified. Seven of these studies presented results adjusted for confounding variables including age and other comorbidities. Of those, two also adjusted for time since the event or event severity. Disutilities ranged from 0.035 to 0.129 for MI and from 0.044 to 0.269 for stroke. One study presented disutilities for an event experienced the previous year (MI, 0.081 - 0.129; stroke, 0.091 - 0.181) and  $> 1$  year ago (MI, 0.042 - 0.078; stroke, 0.069 - 0.269). The study presenting estimates by event severity adjusted for confounding variables had disutilities of 0.044 for stroke or transient ischemic attack without disability and 0.072 for stroke with residual disability. Of the 15 economic evaluations identified that included estimates of disutilities for MI and/or stroke, 12 used values from one of the utility-estimation studies described above. Two used disutilities from US studies in patients with any type of diabetes, and one used general population disutilities. **CONCLUSIONS:** The wide range of utility estimates for MI or stroke in T2DM patients could impact the results of cost-effectiveness analyses for new treatments that avoid or delay these events and calls for research to create consistent estimates, accounting for event severity and valuing event sequelae over time, such as poststroke disability.

#### PDB70

##### PATIENT-REPORTED OUTCOMES (PROS) IN DIABETES CLINICAL TRIALS

Barsdorf AI<sup>1</sup>, Rubinstein E<sup>2</sup>, Jaksa A<sup>2</sup>

<sup>1</sup>Pfizer Inc, New York, NY, USA, <sup>2</sup>Context Matters, Inc., New York, NY, USA

**OBJECTIVES:** To assess prevalence and type of Patient-Reported Outcomes (PROs) in Type 2 Diabetes clinical trials. **METHODS:** A search of www.clinicaltrials.gov was conducted using the search criteria of Type-2 diabetes (T2DM) as the disease and drug as the intervention, in addition to limiting the studies to Phase 3. This resulted in 810 trials. Trials were excluded if any of the following exclusion criteria were met: sample size  $< 50$ , start date before 2000, main condition other than T2DM, and trial did not include clinical outcomes. Phase 2/3 studies, pediatrics trials, and both double-blind and open-label studies were included. The remaining 632 trials were then assessed for prevalence and type of PROs. **RESULTS:** Only 47 (7.4%) of trials in the sample used PROs. There is no discernable trend for PRO use over time. For these 47 trials, 1.9 PROs were used on average, with a range of 1 to 7 PROs. A total of 90 PROs were included in these 47 trials. Forty-three (48%) of these PROs measured Health-Related Quality of Life (HRQL)/Utilities, 22 (24%) measured treatment satisfaction, five (6%) were unknown. Within the HRQL measures, 37% (16) were diabetes-specific, 37% (16) were generic (e.g., SF-36), and the remaining 26% of PROs were not specified. Among treatment satisfaction, 82% were diabetes-specific. Thirty-three (70%) of the studies using PROs were for drugs that are injectables (i.e., not oral). **CONCLUSIONS:** PRO use in T2DM clinical trials remains low. Despite their underuse, the need to assess effectiveness of an intervention from a patient perspective continues to grow in relevance. Although there are a host of diabetes-specific PROs available, the development of a clinical trial-specific, user-friendly instrument may be needed